MAY 2 2 2014

510(k) Summary

This 510(k) Summary for the Chito-SAM™ Gauze (Chito-SAM™ 100 for prescription use and Chito-SAM™ Active for over-the-counter use) is submitted in accordance with the requirements of SMDA 1990 and 21 CFR§807.92.

1.0 GENERAL INFORMATION

Applicant:
SAM Medical Products®
27350 SW 95th Avenue, Suite 3038
Wilsonville, OR 97070
U.S.A.
Phone: 503-639-5474
FAX: 503-639-5425

Contact Person:
Kasey Griffin
Quality Assurance and Regulatory Affairs Manager
SAM Medical Products®
27350 SW 95th Avenue, Suite 3038
Wilsonville, OR 97070
U.S.A.
Phone: 503-639-5474
FAX: 503-639-5425

Date Prepared: April 3, 2014

2.0 DEVICE INFORMATION

Trade Name:
Chito-SAM™ 100 (Prescription use)
Chito-SAM™ Active (Over-the-counter use)

Generic/Common Name:
Hemostatic Dressing

Classification:
Unclassified

Product Code:
FRO

3.0 PREDICATE DEVICES

Each of the following predicate devices is cleared for prescription use and over-the-counter use.

510(k) Number	Product Code	Trade Name	Manufacturer
K080097	FRO	CELOX Hemostatic Granules on Sheet	Medtrade Products Ltd.
K091795	FRO	CELOX Trauma Gauze	Medtrade Products Ltd.
K113560	FRO	CELOX Gauze PRO CELOX Gauze PRO OTC CELOX PRO Hemostatic Gauze OMNI-STAT Granules on Gauze	Medtrade Products Ltd.

4.0 DEVICE DESCRIPTION

The Chito-SAM™ Gauze (refers to both the Chito-SAM™ 100 for prescription use and Chito-SAM™ Active for over-the-counter use) is made of a non-woven fabric derived from chitosan fibers. Chitosan is a naturally occurring polysaccharide usually derived from shellfish, and its hemostatic properties are widely recognized in the biomedical field. When applied directly on a wound with firm pressure, the Chito-SAM Gauze will turn into a gel-like condition to absorb the blood and assist in temporarily controlling moderate to severe bleeding. The Chito-SAM Gauze is provided in three (3) different sizes for prescription use and two (2) different sizes for over-the-counter use to accommodate a variety of treatment regions. The Chito-SAM Gauze is individually packaged in a foil pouch and is gamma-sterilized.

5.0 INDICATIONS FOR USE

Chito-SAM™ 100 (prescription use):

For use as a temporary external dressing to control moderate to severe bleeding and manage external abrasions and lacerations.

Chito-SAM™ Active (over-the-counter use):

To control bleeding of lacerations, minor cuts and abrasions.

6.0 SUBSTANTIAL EQUIVALENCE COMPARISON

The indications for use for the predicate devices is substantially equivalent to the proposed indications for use for the Chito-SAM Gauze. The technological characteristics of the Chito-SAM Gauze are similar to the predicate devices. Available performance data support the determination of substantial equivalence. Any differences in the

technological characteristics between the devices do not raise any new issues of safety or effectiveness. Thus, the Chito-SAM Gauze is substantially equivalent to the predicate devices.

7.0 NON-CLINICAL TESTING

Bench performance testing included functional testing for:

- Liquid Absorption
- pH
- Tensile Strength (wet and dry)
- Platelet Aggregation
- Comparison to predicate devices for each of the above functional characteristics

Biocompatibility testing per ISO 10993-1 was performed for:

- Cytotoxicity
- Skin Irritation
- Skin Sensitization
- Hemolysis
- Acute Systemic Toxicity (intraperitoneal and intravenous)

In-vivo hemostasis testing using the swine model was performed to demonstrate the performance of the Chito-SAM product vs. the predicate devices.

Shelf-life testing, including sterilization validation and packaging testing, confirmed a three-year shelf life for packaged, sterilized product.

The collective results of the bench and animal testing demonstrate that the materials chosen, the manufacturing processes, and design of the Chito-SAM Gauze meet the established specifications necessary for consistent performance during its intended use. In addition, the testing demonstrates that the Chito-SAM Gauze does not raise new questions of safety or effectiveness for its intended use when compared to the predicate devices.

8.0 CLINICAL TESTING

Clinical testing was not required for this submission.

9.0 CONCLUSIONS

The Chito-SAM Gauze shares its design and mechanism of action with the identified predicate devices. The results of the bench testing confirm that the Chito-SAM Gauze functions to its specifications, performs as intended, and exhibits the appropriate characteristics of a wound dressing. The Chito-SAM Gauze is substantially equivalent to the predicate devices in terms of technological characteristics, intended use, and performance. No new issues of safety or effectiveness are raised by the Chito-SAM Gauze.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

May 22, 2014

SAM Medical Products
Mr. Jack McCutcheon
Quality Assurance and Regulatory Affairs Manager
27350 Southwest 95th Avenue, Suite 3038
Wilsonville, Oregon 97070

Re: K133121
Trade/Device Name: Chito-SAM™ Active
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 3, 2014
Received: April 7, 2014

Dear Ms. Griffin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K133121

Device Name: Chito-SAM™ Active

Indications For Use:

Chito-SAM™ Active 100% Chitosan Hemostatic Dressing

To control bleeding of lacerations, minor cuts and abrasions.

Prescription Use _____ (21 CFR Part 801 Subpart D)	And/Or	Over the Counter Use _X_ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Jiyoung Dang -S